Aptar CSP Technologies' Regulatory Track Record

Aptar CSP's 3-Phase Activ-Polymer™ technology has a proven regulatory record and is safe and effective. Aptar CSP Technologies has an extensive record of accomplishment in supporting our partners from R&D to approval in different regions and with different regulatory agencies. The following is an overview of our regulatory record of accomplishment.

Global

Allergens: Labeling Regulations in the US and EU indicate that all food businesses should declare major allergens as specified by the regulatory bodies of those regions.

Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE): Raw material of pharmaceutical products derived from animal sources pose the risk of TSE. This disease can be transmitted to humans from the cattle infected with BSE through pharmaceutical dosage forms. Regulation of TSE/BSE in pharmaceuticals are of great importance due to the effects on human health.

Bisphenol A (BPA): Different regions apply various levels of BPA regulation, with the EU enacting some of the strictest. Specifically, France has banned BPA in all food and beverage packaging and utensils since 2015.

Latex: A portion of the population has a latex allergy whereby the body reacts negatively to the proteins found in latex rubber. Mild reactions to latex involve skin redness, rash, hives, or itching. More severe reactions may involve respiratory symptoms such as runny nose, sneezing, itchy eyes, scratchy throat, and asthma (difficulty breathing, coughing spells, and wheezing).

Heavy Metals: Heavy metals in high doses can be harmful to the body while others, such as cadmium, mercury, lead, chromium, silver, and arsenic, have delirious effects in the body in minute quantities, causing acute and chronic toxicities in humans.

Pesticides: Pesticides can cause short-term adverse health effects, called acute effects, as well as chronic adverse effects that can occur months or years after exposure. Examples of acute health effects include stinging eyes, rashes, blisters, blindness, nausea, dizziness, diarrhea and death. Examples of known chronic effects are cancers, birth defects, reproductive harm, neurological and developmental toxicity, immunotoxicity, and disruption of the endocrine system.

Non-Irradiated: Food irradiation (the application of ionizing radiation to food) is a technology that improves the safety and extends the shelf life of foods by reducing or eliminating microorganisms and insects. Regulation of irradiation of food and packaging is a global standard.

Nanomaterials: Prolonged exposure to nanoparticles can have an adverse effect on human health and the environment.

Phthalates: Phthalates are plastic additives to increase flexibility, also known as plasticizers. They have been found to migrate from non-PVC food contact materials. Exposure to phthalates is of concern, because these substances are linked to reduced fertility, reproductive toxicity and testicular toxicity in animal studies. We perform testing to confirm no presence of phthalates in our products.

GMO: Regulation for GMO labeling varies throughout the world.

North America

Food and Drug Administration (FDA) Food Contact Approval: Mandatory to market or sell products in the US that might have a significant risk of injury or illness but can also benefit your health, such as prescription medications, over-the-counter medications, vaccines and Class III medical devices.

GRAS: "GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is considered a food additive that is subject to pre-market review and approval by the FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

Proposition 65: The Safe Drinking Water and Toxic Enforcement Act of 1986 protects California's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects, or other reproductive harm, and requires businesses to inform Californians about exposures to such chemicals. Proposition 65 requires the state to maintain and update a list of chemicals known by the state to cause cancer or reproductive toxicity.

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Europe

EU 10/2011: The (EU) No. 10/2011 is a specific measure for plastic food contact materials as mentioned in the European Framework Regulation EU 1935/2004. The regulation covers compositional requirements, specific provisions for multi-layer materials, Declaration of Compliance (DoC), provision of specific rules for migration testing and conditions used in the testing programs, and assessment of Non Intentionally Added Substances (NIAS). Requirements include Overall Migration Limits (OML) and Specific Migration Limits (SML).

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH): REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

ISO 13485: ISO 13485 is designed to be used by organizations involved in the design, production, installation and servicing of medical devices and related services. It can also be used by internal and external parties, such as certification bodies, to help them with their auditing processes.

Restriction of Hazardous Substances (RoHS): The goal of RoHS is to reduce the environmental effect and health impact of electronics. The legislation's primary purpose is to make electronics manufacturing safer at every stage of an electronic device's life cycle.

Regulatory Agency	Market Served	Therapeutic Area
US FDA, EMA	Oral Solid Dose	- HIV Pre-Exposure Prophylaxis (PrEP) - Antifungal Treatment
US FDA, EMA, TFDA, CFDA	Probiotic	- Baby Digestive Health - Women's Health - Immune System Health - Daily Care and Wellness
US FDA, EMA, TFDA, CFDA	Medical Device	- Sacral Neuromodulation Therapy - High-frequency Spinal Cord Stimulation
US FDA, EMA, TFDA, CFDA	Diagnostics	- Diabetic Test Strip Packaging - Rapid Testing - Blood Gas Analyzer
EMA	Transdermal	- Hormone Replacement Therapy
US FDA, EMA	Other (Stability of: Powders, Electronics, Test Kits, etc.)	- Vaccine Delivery - Synthetic Bone Graft Material - Force Sensor Stability - Water Quality Test Kits - Dental Alignment Material Stability - Cosmetic Powder